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# TELEFAX

**Date:** November 24, 2004 **Total pages:** 21 with fax cover

**To:** USPTO **Telephone:** **Telefax:** 703-872-9306

**From:** Patrea Pabst **Telephone:** 404-879-2151 **Telefax:** 404-879-2160

**Our Docket No.** MIT 5261
**Your Docket No.** **Client/Matter No.** 701350/48

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**MESSAGE: RESEND WITH CORRECT SERIAL NUMBER ON FAX COVER SHEET (ORIGINALLY SENT Nov. 12, 2004)**
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Paul R. Schimmel

Serial No: 08,249,689 Art Unit: 1714

Filed: May 26, 1994 Examiner: J. Brusca

For: *DESIGNING COMPOUNDS SPECIFICALLY INHIBITING RIBONUCLEIC ACID FUNCTION*

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Total Number of Pages in This Submission | 20 |

| | |
|---|---|
| Application Number | 08/249,689 |
| Filing Date | May 26, 1994 |
| First Named Inventor | Paul R. Schimmel |
| Art Unit | 1631 |
| Examiner Name | J. Brusca |
| Attorney Docket Number | MIT 5261 |

## ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [✓] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please identify below):

Response to Request for Reconsideration of Decision by Board of Patent Appeals and Interferences

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Pabst Patent Group LLP | | |
| Signature | | | |
| Printed name | Patrea L. Pabst | | |
| Date | November 12, 2004 | Reg. No. | 31,284 |

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| Signature | Chandra Russell | | |
| Typed or printed name | Chandra Russell | Date | November 12, 2004 |

PTO/SB/17 (10-04)
Approved for use through 07/31/2006, OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# FEE TRANSMITTAL for FY 2005

*Effective 10/01/2004. Patent fees are subject to annual revision.*

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 0.00

| Complete If Known | |
|---|---|
| Application Number | 08/249,689 |
| Filing Date | May 26, 1994 |
| First Named Inventor | Paul R. Schimmel |
| Examiner Name | J. Brusca |
| Art Unit | 1631 |
| Attorney Docket No. | MIT 5261 |

## METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

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Deposit Account Number: 50-3129

Deposit Account Name: Pabst Patent Group LLP

The Director is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

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## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1001 | 790 | 2001 | 395 | Utility filing fee | |
| 1002 | 350 | 2002 | 175 | Design filing fee | |
| 1003 | 550 | 2003 | 275 | Plant filing fee | |
| 1004 | 790 | 2004 | 395 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

SUBTOTAL (1) ($)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | | Extra Claims | | Fee from below | | Fee Paid |
|---|---|---|---|---|---|---|---|
| Total Claims | 20 | -20 = | 0 | X | 0 | = | 0 |
| Independent Claims | 3 | -3** = | 0 | X | 0 | = | 0 |
| Multiple Dependent | | | | | | = | |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 88 | 2201 | 44 | Independent claims in excess of 3 |
| 1203 | 300 | 2203 | 150 | Multiple dependent claim, if not paid |
| 1204 | 88 | 2204 | 44 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) ($) 0.00

**or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for *ex parte* reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 430 | 2252 | 215 | Extension for reply within second month | |
| 1253 | 980 | 2253 | 490 | Extension for reply within third month | |
| 1254 | 1,530 | 2254 | 765 | Extension for reply within fourth month | |
| 1255 | 2,080 | 2255 | 1,040 | Extension for reply within fifth month | |
| 1401 | 340 | 2401 | 170 | Notice of Appeal | |
| 1402 | 340 | 2402 | 170 | Filing a brief in support of an appeal | |
| 1403 | 300 | 2403 | 150 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,370 | 2501 | 685 | Utility issue fee (or reissue) | |
| 1502 | 490 | 2502 | 245 | Design issue fee | |
| 1503 | 660 | 2503 | 330 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 790 | 2809 | 395 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 790 | 2810 | 395 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 790 | 2801 | 395 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

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| SUBMITTED BY | | | | (Complete *(if applicable)*) | |
|---|---|---|---|---|---|
| *Name (Print/Type)* | Patrea L. Pabst | *Registration No. (Attorney/Agent)* | 31,284 | *Telephone* | (404) 879-2151 |
| *Signature* | | | | *Date* | November 12, 2004 |

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | |
|---|---|---|---|
| Appellant: | Paul R. Schimmel | Appeal No. | 2003-1335 and 1997-2396 |
| Serial No.: | 08/249,689 | Art Unit: | 1631 |
| Filed: | May 26, 1994 | Examiner: | J. Brusca |

For: *"DESIGNING COMPOUNDS SPECIFICALLY INHIBITING RIBONUCLEIC ACID FUNCTION"*

Board of Patent Appeals and Interferences
Washington, D.C. 20231

**RESPONSE TO REQUEST FOR RECONSIDERATION OF DECISION BY BOARD OF PATENT APPEALS AND INTERFERENCES**

Sirs:

Appellant requests the Board deny the request for reconsideration of the decision by the Board of Patent Appeals and Interferences mailed October 30, 2003.

Please address all future correspondence to:

**Patrea L. Pabst**
**PABST PATENT GROUP LLP**
**400 Colony Square Suite 1200**
**1201 Peachtree Street**
**Atlanta, GA 30361**
**(404) 879-2151 (Telephone)**
**(404) 879-2160 (Fax)**

It is believed that no fee is required. However, should a fee be required, the Commissioner is hereby authorized to charge the additional fees to Deposit Account No. 50-3129. A change of correspondence address has been filed.

U.S.S.N. 08/249,689
FILED: May 26, 1994
RESPONSE TO REQUEST FOR RECONSIDERATION OF
DECISION BY BOARD OF PATENT APPEALS AND INTERFERENCES

## I. Brief History of Appeals in this Application

This application was originally filed May 26, 1994, claiming priority as a continuation to U.S.S.N. 07/586,534 filed September 21, 1990. The examiner's rejection of the claims under 35 U.S.C. 112 as lacking enablement was originally appealed August 19, 1996. A decision in appeal 1997-2396, mailed on April 30, 2001, by the Board of Appeals reversed the rejection of the method and composition claims under 35 U.S.C. 112, finding the claims enabled, upheld the double patenting rejection over the related case, 07/929,834 filed August 14, 1992, issued September 3, 2002 as U.S. Patent No. 6,446,032, and made a new rejection under 35 U.S.C. 112, written description. The Board's decision in appeal 1997-2396, held that, while the factors relied on by the examiner are relevant in determining enablement by the specification, they were insufficient to establish that the experimentation required to practice the claimed invention was undue. The examiner's rejection of claims 1 and 3 through 21 for lack of enablement under 35 U.S.C. § 112, first paragraph, was reversed. Under the provisions of 37 C.F.R. § 1.196(b), the Board entered a new ground of rejection under the first paragraph of 35 U.S.C. § 112 on the basis that the specification failed to provide an adequate written description for composition claims 11 through 13, 17 through 19 and 21.

In response to the Board's decision dated April 30, 2001, Appellant amended base claim 11, and claims dependent thereon, to more clearly define the composition as a compound that is complementary to the target RNA sequence comprising hydrogen bond donor and acceptor sites.

Lines 29-17, bridging pages 38 and 39, for example, provide support for these amendments. A Terminal Disclaimer was also filed.

The examiner rejected the amended composition claims as lacking written description. Appellant submitted argument and factual and expert evidence. The examiner maintained the rejection. The examiner's final rejection of composition claims 11-13, 17-19 and 21 under 35 U.S.C. 112, as lacking written description was appealed to the Board of Appeals on June 10, 2002. On October 30, 2003, the Board of Appeals affirmed the rejection in part and reversed in part and the case was returned to the examiner.

The method claims are allowable.

After numerous calls to the examiner, this request for reconsideration was issued.

## II. Basis for Request for Reconsideration

The alleged basis for the request for reconsideration is that there was an intervening decision by the Court of Appeals for the Federal Circuit, *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 USPQ 1886 (Fed. Cir. 2004) that was not considered by the Board of Appeals in rendering its decision on October 30, 2003. The request also states that the Board's analogy to antibody-antigen binding is technically incorrect. The request mischaracterizes the claims (including the allowed method claims) and ignores the abundance of evidence and case law that the Board did take into consideration, not once but twice with this case on appeal.

Although the Appellant would have preferred for the Board to have reversed the rejection of all claims, the Board did not fail to consider the evidence and to utilize the correct standard of law in making its decision. The Board as clearly done a far better job of reviewing the application, the record and the evidence than those requesting the Board now reverse its decision. These facts are briefly reviewed below along with an analysis of the legal standard for compliance with the written description requirement. A careful review of the decision in *University of Rochester* makes clear that the legal standard for written description was not altered by the Federal Circuit, but clarified as to application to the very specific set of facts in *University of Rochester.*

**III. Status of Claims**

Claims 1, 3, 4, 5, 6, 7, 8, 9, 10, 14, 15, 16, and 20 are pending and allowed.

Claim 11 was amended on December 24, 2003, to incorporate the language of claim 17, which was found to comply with the requirements of 35 U.S.C. 112 by the Board of Appeals in its decision issued October 30, 2003. Claims 13, 18, 19 and 21 depend from claim 11.

Claim 2, 12 and 17 have been cancelled.

The claims in issue are as follows:

11. A complementary compound comprising hydrogen bond donor and acceptor sites arranged to specifically bind and inhibit the function of a targeted RNA molecule, wherein the compound is specifically directed to and binds to a critical region within the minor groove of the

acceptor stem of a tRNA molecule, identified by a combination of the primary, secondary and tertiary structure of the critical region.

12. The complementary compound of claim 11 wherein the RNA is selected from the group consisting of mRNA, tRNA, rRNA, and viral RNA.

13. The complementary compound of claim 11 further comprising a pharmaceutically acceptable carrier selected from the group consisting of pharmaceutically acceptable compositions for topical administration, pharmaceutically acceptable compositions for parenteral administration, pharmaceutically acceptable compositions for enteral administration, and combinations thereof.

18. The complementary compound of claim 11 wherein the tRNA molecule is $tRNA^{Ala}$.

19. The complementary compound of claim 11 wherein the critical region is the G3:U70 base pair.

21. The complementary compound of claim 11 wherein the compound is a nucleic acid and the compound is synthesized *in vivo* from a retroviral vector.

**IV. The Application and Evidence Comply with the Written Description Requirement**

The request for reconsideration is factually incorrect on two basis: (1) the claims define a composition with a specific structure and function based on its complementarity and binding to the acceptor stem of the minor groove of a tRNA molecule and (2) the claimed composition and its substrate is analogous to antibody-antigen binding. The request for reconsideration is also

misleading in how it characterizes the claims in issue and fails to consider the supplemental evidence provided by the appellant.

Claim 11 defines "A **complementary compound** comprising **hydrogen bond donor and acceptor sites arranged to specifically bind and inhibit the function of** a targeted RNA molecule, wherein the compound is specifically directed to and binds to **a critical region within the minor groove of the acceptor stem of a tRNA molecule, identified by a combination of the primary, secondary and tertiary structure of the critical region.**" (emphasis added)

The Board found this language to be supported by the application since "the structure of at least one of the two mutually dependent compounds, in this case, the RNA target molecules, is 'sufficiently known or disclosed'. That is, in claim 17, the target RNA is identified as the acceptor stem of a tRNA molecule; in claim 18 the target RNA is the $tRNA^{Ala}$ molecule; and in claim 19, the target is identified as the G3:U70 base pair of the $rTNA^{Ala}$ molecule. Thus, for the subject matter of these claims, a functional characteristic (binding and inhibition of target RNA) is coupled with 'a structure that is sufficiently known or disclosed' (a transfer RNA)". Decision at page 7.

**As the Board correctly found, appellant demonstrated in the application as originally filed, that the primary, secondary and tertiary structure of the tRNA molecules were known, methods to make and screen for inhibitors were known; and inhibition of function through alteration of structure within the acceptor stem of a tRNA had been demonstrated as of the date this application was originally filed. See page 3, line 15 to page 4, line 4; Figures 1A, 2A, 2B, 3 and 4; page 8, lines 7-20 and line 23 to page 8, line 2; page**

**12, line 11 to page 14, line 22; page 15, lines 5-24; pages 16-17 (screening method); pages 20-22; examples 1 and 3, describing not just the native tRNA molecules but a number of variants; example 6, describing an inhibitor for bacterial but not human tRNA with reference to Figures 3 and 4.**

The claims define compounds complementary to the minor groove of the acceptor stem of a tRNA molecule. If anything, this is even more exact than the relationship between antibody and antigen, since antibodies have a variable region that differs depending upon the antigen that is bound by the antibody. In the case of the acceptor stem of a tRNA molecules, there is no variation. The primary, secondary and tertiary structures are all known. The claimed compounds are therefore defined by their complementarity to a specific portion of these known, well characterized molecules and by their function in inhibiting the tRNA molecules through binding to the minor groove.

The claims on appeal were drawn to a genus of compounds complementary to a targeted RNA molecule and inhibiting the function of the targeted RNA molecule. Following the decision, the claims were narrowed to those compounds complementary to the minor groove of the acceptor stem of a tRNA molecules. The specification describes the structure of the claimed compounds by illustrating the chemical properties (hydrogen bond acceptor and donor sites arranged specifically) and method of preparation (first, determining the target RNA sequence and second, preparing the compounds accordingly) of the compounds, along with that of the minor groove of the acceptor stem of the tRNA molecules. These elements distinguish the

compounds based on the claimed interaction with a critical region in the minor groove of the target RNA. Although the compounds may be organic, inorganic, proteins, or even nucleic acids, specific binding is achieved through complementary interactions (page 38 of the specification, lines 24-31). These interactions are dependent upon hydrogen bonding (lines 29-17, bridging pages 38 and 39). Therefore, in order for the compound to bind to the target RNA, hydrogen bond donor sites, hydrogen bond acceptor sites, and chemical side groups, have to be in the correct spatial location, orientation, and have the correct charge. One of skill in the art would realize that it is this arrangement that defines the structure of the compound. "Complementary" defines the structure of the compound. Complementary compounds are limited by the primary, secondary and tertiary structure of the RNA target molecule.

The importance of appellant's discovery cannot be underestimated: he discovered that RNA inhibitors must bind to their RNA target within the minor groove, and can be designed based on the secondary and tertiary structure of the RNA within this minor groove. This is the subject matter of the method claims that have been allowed. He provided the specific structure of the inhibitors of the minor groove of the acceptor stem of tRNA molecules by reference to the known structure of this site. Many others have since made RNA inhibitors that bind to the minor groove. Appellant previously submitted Declarations by two experts in the field to show that they considered the application complied with the written description requirement, and that one of routine skill would need nothing more than what is in the application to know that appellant had possession of the claimed genus at the time of filing. The Examiner never provided any

rebuttal evidence, only argument in denying that those skilled in the art at the time this application was filed knew or could readily ascertain the structure of the claimed compounds, based on their complementarity to the minor groove of RNA molecules, using available computer software programs. What appellant discovered, and made available to the public, was the evidence that the inhibitor had to fit within the minor groove, bind by hydrogen bonds and have complementary structure to the RNA within the minor groove.

Two declarations under 37 C.F.R. § 1.132 by Dr. Jules Rebek and Dr. James R. Williamson, respectively, were submitted with the response mailed on April 11, 2002. Both Dr. Rebek and Dr. Williamson are experts in the field. Neither have any financial interest in this application nor received any compensation for their declaration. Dr. Williamson provided his expert opinion as well as enclosed data in support of the claims. The declarations were submitted in order to provide further evidence that the description of the structure of the critical region in the minor groove of RNA is sufficient to describe the structure of the claimed compound. Each declaration clearly elaborates upon the present specification's discussion of the forces presented in and by the targeted RNA molecule. While these forces establish the structure of the critical region of the RNA in terms of specific and available interactions and geometry, they are a direct result of the RNA sequence (primary structure). Secondary and tertiary structures can subsequently be determined via any number of commercially available programs, as outlined in the submitted declarations.

The analogy to a "lock and key", in the submitted declarations, is an important one because if one can conceptualize the role of the predetermined and defined target RNA in demanding a specific structure of the inhibitory compound, then one will realize that the compound structure is clearly defined. The target RNA is defined by those interactions and forces present in the minor groove of the critical region, as described in the specification, defined by the claims and further elaborated on by Drs. Jules Rebek and James R. Williamson. The statements that this is a situation totally unlike that of an antibody-antigen relationship is factually incorrect. The minor groove of the acceptor stem of a tRNA has a known and defined primary, secondary and tertiary structure. This was known at the time the application was filed. The claimed compounds bind within this groove by virtue of the three dimensional structure that conforms to the shape of the minor groove and the chemical composition that creates hydrogen bonding at sites within the minor groove that are readily ascertainable. This is the exact same way an antigen is bound by the variable region of an antibody.

Dr. Rebek

Dr. Rebek is the Director of the Skaggs Institute of Chemical Biology and Professor of Chemistry of the Scripps Research Institute. Dr. Rebek is clearly an expert in the field of nucleic acid structure. Dr. Rebek has no personal or financial interest in this application. He was asked to review the specification and claims, in view of the legal standard for the written description under 35 U.S.C. §112, to determine if he, as one in the field, would know what the structure of the claimed compounds was, based on his knowledge, the specification, and the language of the

claims. Dr. Rebek specifically addressed the structure of the minor groove of the RNA in responding, reviewing the hydrophobic environment of the minor groove, hydrogen bonding, electrostatic interactions, and geometric and steric constraints. As summarized on page 7, "All of these 'constraints' define the nature of the inhibitory compound in terms of structure and functionality; they define the molecular recognition of the RNA by the compound where the compound is complementary in size, shape and chemical surface to the RNA."

Dr. Williamson

Dr. Williamson is a Professor of Molecular Biology and Chemistry at the Scripps Research Institute in La Jolla, CA. He is an expert in the field of RNA and drug design, including RNA structure, RNA-protein recognition, and RNA-small molecule interaction. As stated at the top of page 3, he presents "evidence indicating that attractive and repulsive forces present in the critical region of the minor groove of RNA dictate or define the geometrical constraints of the region. These forces, as described in the specification, and below, define the structure of the critical region in a way that provides one with a mental picture of a defined "space" that can only be accessed by a compound of the correct "shape". He also reviews each of the claimed structural features: the hydrophobic environment of the minor groove, the hydrogen bonding, the electrostatic interactions, and the geometic and steric constraints. Dr. Williamson refers to the precedent of compounds that bind to DNA molecules (recognizing that here, the invention is the discovery that the minor groove of RNA is the critical binding site, whereas in DNA it is the major groove), as published by Dervan, et al., in Science 232, 464-471

(1986). Dr. Williamson also provides evidence that the claimed method and compounds were enabled and clearly described in view of his own subsequent work, published in part by Sultan, et al., Science 288, 107-112 (2000) and as demonstrated by the attached figures.

This evidence clearly support appellant's position that the specification and claims to compounds binding to the minor groove of tRNA molecules and thereby inhibiting the tRNA function meet the requirements under 35 U.S.C. §112, written description. The examiner has never provided anything to rebut this evidence, merely unsupported argument.

## V. The Legal Standard for Compliance with Written Description Requirement

The request for reconsideration is allegedly based on the assertion that the decision in this appeal would have been different had the Board of Patent Appeals and Interferences had the decision by the Federal Circuit in *University of Rochester supra* been available to it. We disagree. The decision by the Board in this case, issued on October 30, 2003, is entirely consistent with the Federal Circuit's decision in *University of Rochester*, especially when the differences in the facts of the two cases are taken into consideration.

In *University of Rochester*, the District Court had found claims to a method of treatment and claims to compounds for use in the method of treatment invalid as lacking enablement and written description. Enablement is not in issue here. The original rejection of the method and compound claims as lacking enablement was reversed by the Board of Appeals in the decision rendered April 30, 2001. This rejection was not made again by the examiner, nor asserted in the

request for reconsideration. One can therefore conclude that all parties are in agreement that one of ordinary skill in the art is able to practice the claimed method and make the claimed compounds, without undue experimentation, unlike in *University of Rochester*.

In *University of Rochester* at 920, the Federal Circuit reviewed the standard of the written description requirement under 35 U.S.C. 112 and reiterated that the purpose of the written description requirement is separate from the enablement requirement, and "is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventors's contribution to the field of art as described in the patent specification,' *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 at 1345 (Fed. Cir. 2000). "The 'written description' requirement serves a teaching function, as a '*quid pro quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time', citing to *Enzo Biochem, Inc. v. Gen-Probe Inc*, 323 F.3d 956 at 970 (Fed. Cir. 2002). *University of Rochester* at 922.

This is another point in which the facts of the present case differ from *University of Rochester*. In the present case, the invention is the discovery that compounds complementary to the minor groove of the acceptor stem of a tRNA molecule can be used to inhibit the activity of the tRNA. The primary, secondary and tertiary structure of the acceptor stem of tRNA molecules, including the minor groove, was known as of the original filing date. The structure of the claimed compounds is defined by this complementarity. The invention is not the structure of the minor groove of tRNA. This was known. The application contains evidence showing that

substitution of even a single nucleotide, i.e., even an extremely small structural change, can inhibit the function of the tRNA molecule. The application and subsequently provided information by two experts in the field at the time this application was filed, establishes that one skilled in the art would have known what compounds could be made that would have been complementary to these known tRNA minor groove structures and would be able to predict their structure and form therefrom. Therefore, unlike in *University of Rochester*, where there was no definition of the structure of the claimed compounds, only a functional definition, the claimed compounds in this case are defined by structure and by function, and those skilled in the art have provided unrebutted evidence that they could be obtained and characterized without undue experimentation.

The Court in *University of Rochester* did not change its previous interpretation of the requirements for compliance with the written description requirement, reiterated shortly before in *Enzo supra*. The Board's attention is drawn in particular to the Court's statement in *University of Rochester* at 925, citing again to *Enzo* and stating "in fact, where there might be some basis for finding a written description requirement to be satisfied in a genetics case based on the ***complementariness*** of a nucleic acid and, for example, a protein, that correspondence might be less clear in a non-genetic situation. In *Enzo*, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are 'coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.' 323 F.3d at 964 (quoting from the PTO's

U.S.S.N. 08/249,689
FILED: May 26, 1994
RESPONSE TO REQUEST FOR RECONSIDERATION OF
DECISION BY BOARD OF PATENT APPEALS AND INTERFERENCES